



08-20-07

IFW

Express Mail No.: EV473972095US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Zeldis et al.

Confirmation No.: 2198

Application No.: 10/576,152

Filed: April 17, 2006

Group Art Unit: 1623

For: METHODS FOR TREATMENT,  
MODIFICATION AND MANAGEMENT OF  
PAIN USING 1-OXO-2-(2,6-  
DIOXOPIPERIDIN-3-YL)-4-  
METHYLISOINDOLINE

Examiner: To be assigned

Attorney Docket No.: 9516-313-999  
(501872-999312)**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. §1.56 AND §1.97**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and § 1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Attorneys for Applicants hereby invite the Examiner's attention to the references **A01-A87, B01-B05 and C01-24** listed on the attached Substitute For form 1449/PTO entitled "Information Disclosure Statement by Applicant." Copies of references **B01-B05 and C01-24** are submitted herewith. Copies of references **A01-A87**, being U.S. patents or publications, are not submitted herewith pursuant to 37 C.F.R. § 1.98(a)(2)(ii).

Identification of the listed references is not meant to be construed as an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application.

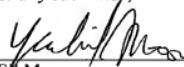
Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

Pursuant to 37 C.F.R. § 1.97(b), Applicants estimate that no fee is due in connection with the filing of this Information Disclosure Statement. However, should the Patent Office determine otherwise, please charge the necessary fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: August 17, 2007

(Reg. No.)

  
Yeah-Sub Moon

52,042

JONES DAY  
222 East 41<sup>st</sup> Street  
New York, New York 10017-6702  
(212) 326-3939

Enclosures

Substitute for Form 1449/PTO		ATTY DOCKET NO. 9516-313-999	APPLICATION NO. 10/576,152
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT: Zeldis et al.	
		FILING DATE: April 17, 2006	ART UNIT: CONF. NO.: 1623 2198

*AUG 17 2007*

U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*	DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A01	2002/0045643	4/18/2002	Muller et al.	
A02	2003/0045552	3/6/2003	Robarge et al.	
A03	2003/0096841	5/22/2003	Robarge et al.	
A04	2004/0038874 A1	2/26/2004	Omoigui	
A05	3,536,809	10/27/1970	Applezweig	
A06	3,598,123	8/10/1971	Zaffaroni	
A07	3,845,770	11/5/1974	Theeuwes et al.	
A08	3,916,899	11/4/1975	Theeuwes et al.	
A09	4,008,719	2/22/1977	Theeuwes et al.	
A10	5,059,595	10/22/1991	La Grazie	
A11	5,073,543	12/17/1991	Marshall et al.	
A12	5,120,548	6/9/1992	McClelland et al.	
A13	5,134,127	7/28/1992	Stella et al.	
A14	5,354,556	10/11/1994	Sparks et al.	
A15	5,591,767	1/7/1997	Mohr et al.	
A16	5,593,990	1/14/1997	D'Amato	
A17	5,629,327	5/13/1997	D'Amato	
A18	5,635,517	6/3/1997	Muller et al.	
A19	5,639,476	6/17/1997	Oshlack et al.	
A20	5,674,533	10/7/1997	Santus et al.	
A21	5,698,579	12/16/1997	Muller	
A22	5,703,092	12/30/1997	Xue, et al.,	
A23	5,733,566	3/31/1998	Lewis	
A24	5,798,368	8/25/1998	Muller et al.	
A25	5,874,448	2/23/1999	Muller et al.	
A26	5,877,200	3/2/1999	Muller	
A27	5,929,117	7/27/1999	Muller et al.	
A28	5,955,476	9/21/1999	Muller et al.	
A29	6,071,948	6/6/2000	D'Amato	
A30	6,281,230	8/28/2001	Muller et al.	

EXAMINER NYI-3926405v1	/Patrick Lewis/ (09/15/2009)	DATE CONSIDERED
---------------------------	------------------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.L./ (09/15/2009)

Substitute for Form 1449/PTO		ATTY DOCKET NO. 9516-313-999	APPLICATION NO. 10/576,152
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)			APPLICANT: Zeldis et al.
		FILING DATE: April 17, 2006	ART UNIT: CONF. NO.: 1623 2198

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*	DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A31	6,316,471	11/13/2001	Muller et al.	
A32	6,335,349	1/1/2002	Muller et al.	
A33	6,380,239	4/30/2002	Muller et al.	
A34	6,395,754	5/28/2002	Muller et al.	
A35	6,403,613	6/11/2002	Man et al.	
A36	6,458,810	10-01--02	Muller et al.	
A37	6,476,052	11/5/2002	Muller et al.	
A38	6,555,554	4/29/2003	Muller et al.	
A39	6,635,250	10/21/2003	Olmarker et al.	
A40	2003/0235909	12/25/2003	Hariri et al.	
A41	2003/0191098	10/9/2003	D'Amato	
A42	2003/0187024	10/2/2003	D'Amato	
A43	2002/0183360	12/5/2002	Muller et al.	
A44	2003/181428	9/25/2003	Green et al.	
A45	2002/0173658	11/21/2002	Muller et al.	
A46	2002/0161023	10/31/2002	D'Amato	
A47	2003/0144325	7/31/2003	Muller et al.	
A48	2003/0139451	7/24/2003	Shah et al.	
A49	2004/0122052	6/24/2004	Muller et al.	
A50	2004/0091455	5/13/2004	Zeldis	
A51	2004/0087546	5/6/2004	Zeldis	
A52	2004/0077686	4/22/2004	Dannenberg et al	
A53	2004/0077685	4/22/2004	Figg et al.	
A54	2003/069428	4/10/2003	Muller et al.	
A55	2002/0061923	5/23/2002	D'Amato	
A56	2001/0056114	12/27/2001	D'Amato	
A57	2002/0054899	5/2/2002	D'Amato	
A58	2002/0052398	5/2/2002	D'Amato	
A59	2004/0029832	2/12/2004	Zeldi	

NYI-3926405v1

EXAMINER	/Patrick Lewis/ (09/15/2009)	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.L./ (09/15/2009)

Substitute for Form 1449/PTO  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY DOCKET NO.	APPLICATION NO.
	9516-313-999	10/576,152
	APPLICANT: Zeldis et al.	
	FILING DATE: April 17, 2006	ART UNIT: CONF. NO.: 1623 2198

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*	DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A60	2003/0028028	2/6/2003	Man et al.	
A61	5,385,901	1/31/1995	Kaplan, et al.	
A62	5,712,291	1/27/1998	D'Amato	
A63	6,228,879	5/8/2001	Green, et al.	
A64	6,420,414	7/16/2002	D'Amato	
A65	6,469,045	10/22/2002	D'Amato	
A66	6,673,828	1/6/2004	Green, et al.	
A67	4,215,114	7/7/1980	Szmuškovič et al.	
A68	2003/0185826	10/2/2003	Tobinick	
A69	2003/0113318	6/19/2003	Tobinick	
A70	2003/0049256	3/13/2003	Tobinick	
A71	2003/0007972	1/9/2003	Tobinick	
A72	2002/0131955	9/19/2002	Tobinick	
A73	2002/0131954	9/19/2002	Tobinick	
A74	2001/0026801	10/4/2001	Tobinick	
A75	2001/0016195	8/23/2001	Tobinick	
A76	2001/0004456	6/21/2001	Tobinick	
A77	6,623,736	9/23/2003	Tobinick	
A78	6,537,549	3/25/2003	Tobinick	
A79	6,471,961	10/29/2002	Tobinick	
A80	6,428,787	8/6/2002	Tobinick	
A81	6,423,321	7/23/2002	Tobinick	
A82	6,419,944	7/16/2002	Tobinick	
A83	6,419,934	7/16/2002	Tobinick	
A84	6,379,666	4/30/2002	Tobinick	
A85	6,177,077	1/23/2001	Tobinick	
A86	6,015,557	1/18/2000	Tobinick et al.	
A87	2003/0087962	05/08/2003	Demopoulos et al.	

NYI-3926405v1

EXAMINER	/Patrick Lewis/ (09/15/2009)	DATE CONSIDERED
----------	------------------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.L./ (09/15/2009)

Substitute for Form 1449/PTO		ATTY DOCKET NO. 9516-313-999	APPLICATION NO. 10/576,152
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		APPLICANT: Zeldis et al.	
		FILING DATE: April 17, 2006	ART UNIT: CONF. NO.: 1623 2198

### FOREIGN PATENT DOCUMENTS

EXAMINER'S INITIALS*	Country Code, Number, Kind of Code (if known)	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	TRANSLATION	
					YES	NO
B01	WO 98/03502	1/29/1998	PCT			
B02	WO 98/54170	12/3/1998	PCT			
B03	WO 00/18409	4/6/2000	PCT			
B04	WO 02/059106	8/1/2002	PCT			
B05	WO03086373	10/23/2003	PCT			

### NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s)s, volume, publisher, city and/or country where published., etc.)

EXAMINER'S INITIALS*	NON PATENT LITERATURE DOCUMENTS
C01	Abbott, F. et al. <i>Pain</i> 60:91-102 (1995)
C02	Arruda, Janice L. et al., <i>Brain Research</i> , 879, 216-225, 2000
C03	Bennett G J, <i>Clinical journal of pain</i> , 16(3 Suppl) S139-143, 2000
C04	Toussirot E., et al., <i>Expert opinion on investigational drugs</i> , 10(1), 21-9, Jan. 2001
C05	Carstensen, Jens T., <i>Drug Stability: Principles &amp; Practice</i> , 2d. Ed., Marcel Dekker, NY, NY, 1995, pp. 379-80
C06	Corral, L.G. et al., <i>Ann. Rheum. Dis.</i> 58:(Suppl 1) 1107-1113 (1999)
C07	Dray, A., <i>British Journal of Anaesthesia</i> , 75: 125-131, 1995
C08	Dzwierzynski et al., <i>Hand Clinics</i> Vol 10 (1): 29-44 (1994)
C09	Feng Huang, et al., <i>Arthritis and rheumatism</i> , 47(3), 249-54, Jun. 2002
C10	George, et al., <i>Pain</i> , 88, 267-275, 2000
C11	Hogan, Q., <i>Regional Anesthesia and Pain Medicine</i> 27(4):385-401 (2002)
C12	Langerman et al., <i>Pharmacol. Toxicol. Methods</i> 34:23-27 (1995)
C13	Malmberg, A. and Yaksh, T., <i>Pain</i> 60:83-90 (1995)
C14	Miller, J.M., et al., <i>Antibiot. Med. Clin. Ther.</i> , 7, 743-746, 1960
C15	Perez R.S., et al., <i>J Pain Symptom Manage</i> 2001 Jun; 21(6): 511-26
C16	Rajkumar, S.V., et al., <i>Archives of internal medicine</i> , 161, 2502-3, Nov. 2001
C17	Schwartzman R.J., <i>N Engl J Med</i> 343(9): 654 (2000)
C18	Schwartzman R.J., <i>Curr Opin Neurol Neurosurg</i> 6(4): 531-6 (1993)

NYI-3926405v1

EXAMINER	/Patrick Lewis/ (09/15/2009)	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

Substitute for Form 1449/PTO	ATTY DOCKET NO. 9516-313-999	APPLICATION NO. 10/576,152
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	APPLICANT: Zeldis et al.	
	FILING DATE: April 17, 2006	ART UNIT: CONF. NO.: 1623 2198

**NON PATENT LITERATURE DOCUMENTS** (include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s)s, volume, publisher, city and/or country where published, etc.)

EXAMINER'S INITIALS*	
C19	I Burger's Medicinal Chemistry and Drug Discovery, 172-178, 949-982 (Manfred E. Wolff ed., 5th ed. 1995)
C20	N. Ake Jonsson, 1972, "Chemical Structure and Teratogenic Properties," Acta Pharm., pp. 521-542
C21	Ji, 2003, "Activation of MAP kinases in primary sensory neurons," Proc. 10 <sup>th</sup> World Congress on Pain, Prog. in Pain Res. and Management Vol. 24, Ch. 8, pp. 81-87
C22	Kenney et al., 1998, "Peripheral axotomy induces long-term c-Jun amino-terminal kinase-1 activation and activator protein-1 binding activity by c-Jun and junD in adult rat dorsal root ganglia <i>In vivo</i> ," J. Neurosci. 18(4):1318-1328
C23	Ma et al., 2002, "Partial sciatic nerve ligation induces increase in the phosphorylation of extracellular signal-regulated kinase (ERK) and c-Jun N-terminal kinase (JNK) in astrocytes in the lumbar spinal dorsal horn and the gracile nucleus," Pain 99(1-2):175-184
C24	Wagner et al., "Edoneurial injection of TNF-alpha produces neuropathic pain behaviors," Neuroreport, 1996 Nov 25;7(18):2897-901

NYI-3926405v1

EXAMINER /Patrick Lewis/ (09/15/2009)	DATE CONSIDERED
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /P.L./ (09/15/2009)